

General shall publish in the Federal Register proposed modifications to existing safe harbors and proposed additional safe harbors if appropriate with a 60-day comment period. After considering any public comments received during this period, the Secretary shall issue final rules modifying the existing safe harbors and establishing new safe harbors, as appropriate.

"(C) REPORT.—The Inspector General of the Department of Health and Human Services (in this section referred to as the Inspector General) shall, in an annual report to Congress or as part of the year-end semiannual report required by section 5 of the Inspector General Act of 1978 (5 U.S.C. App.), describe the proposals received under clauses (i) and (ii) of subparagraph (A) and explain which proposals were included in the publication described in subparagraph (B), which proposals were not included in that publication, and the reasons for the rejection of the proposals that were not included.

"(2) CRITERIA FOR MODIFYING AND ESTABLISHING SAFE HARBORS.—In modifying and establishing safe harbors under paragraph (1)(B), the Secretary may consider the extent to which providing a safe harbor for the specified practice may result in any of the following:

"(A) An increase or decrease in access to health care services.

"(B) An increase or decrease in the quality of health care services.

"(C) An increase or decrease in patient freedom of choice among health care providers.

"(D) An increase or decrease in competition among health care providers.

"(E) An increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

"(F) An increase or decrease in the cost to Federal health care programs (as defined in section 1128B(n))

"(G) An increase or decrease in the potential overutilization of health care services.

"(H) The existence or nonexistence of any

potential
financial benefit to a health care professional
or provider
which may vary based on their decisions of—
 "(i) whether to order a health care
 item or
 service; or
 "(ii) whether to arrange for a referral of health
 care items or services to a particular practitioner or
 provider.
 "(I) Any other factors the Secretary deems appropriate
in the interest of preventing fraud and abuse in Federal
health care programs (as so defined).
"(b) ADVISORY OPINIONS —
 "(1) ISSUANCE OF ADVISORY OPINIONS — The
Secretary, in
consultation with the Attorney General, shall
issue written
advisory opinions as provided in this subsection.
 "(2) MATTERS SUBJECT TO ADVISORY OPINIONS —
The Secretary shall issue advisory opinions as to the
following matters:
 "(A) What constitutes prohibited
remuneration within
the meaning of section 1128B(b).